REMARKS

Claims 3, 11, 12, 13, 14, 17, 18, 19, 20, 22, 28, 29, 30, 31, 32, 33, 34, 35, 36, 44, 47, 48, and 49 have been cancelled. Claims 4, 23, and 40-43 have been amended. Now claims 50-57 have been added. Claims 1-2, 4-10, 15-16, 21-23-27, 37-43 and 50-57 are now pending in the application. No new matter has been added by amendment. Reexamination and reconsideration of the claims as amended are respectfully requested.

CLAIM OBJECTIONS

4.) The Examiner objects to claim 25 because it depends from a rejected claim. The rejected claim, 23, has been amended and is now in proper form. The Applicant requests reconsideration of claim 25.

REJECTIONS UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

5.) The Examiner rejects claims 3, 5, 22-24, and 40-44 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner rejects claims 3 and 22. The claims have been cancelled and new claims 50-57 which are in product-by-process form have been added.

The Examiner rejects claims 5 and 24 for improper antecedent basis. Claims 4 and 23 have been amended thus providing proper antecedent basis. Claim 23 has been amended and is now in proper form.

The Examiner rejects claim 40 and states that "the claim is indefinite because the recitation "comprising" in line 1 does not clearly indicate how many crosses are to be performed by the method." Applicant has amended claim 40. The method now refers to the "first generation F1 PH3AV-derived maize plant".

REJECTIONS UNDER 35 USC § 112, FIRST PARAGRAPH

6.) The Examiner rejects claims 9-20, 28-39, 41-43, and 47-49 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor(s), at the time the application was filed, had

possession of the claimed invention. The Applicant traverses the rejection. Claims 11, 12, 13, 14, 17, 18, 19, 20, 28, 29, 30, 31, 32, 33, 34, 35, 36, 47, 48, and 49 have been cancelled. Claims 40-43 have been amended. New claims 50-57 have been added.

The Examiner rejects claims 9, 10, 28, and 29, that claim the F1 hybrid seed and F1 hybrid plant made with PH3AV as a parent. Applicant has cancelled claims 28 and 29. Applicant notes that a claim to the F1 hybrid made with a deposited inbred was expressly acknowledged without reservation by the United States Supreme Court In *J.E.M. Ag. Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 60 USPQ 2d 1865,1873 (S.Ct. 2001), when the Supreme Court wrote, "...a utility patent on an inbred plant line protects the line as well as all hybrids produced by crossing that inbred with another plant line." Further, one of ordinary skill in the art would know how to cross PH3AV with another maize plant. The F1 hybrid seed and plant produced using PH3AV, regardless of the other maize plant used, is identifiable because it will have one set of alleles coming from PH3AV. One of ordinary skill in the art would be able to run a molecular profile on PH3AV and the F1 hybrid and be able to identify the F1 hybrid as being produced from PH3AV. Seed pericarp tissue, which is solely maternal in origin, can be used to discern the maternal or paternal origin of the allele sets if necessary. See page 16 of Poethig, R.S. 1982. Maize, the plant and its parts. In: W.F. Sheridan (Ed.) Maize for Biological Research, University of North Dakota Press, Grand Forks, ND. pp. 9-18, submitted as Appendix A.

As stated in the specification on page 15, lines 8-23, there are many laboratory-based techniques available for the analysis comparison and characterization of plant genotype such as Restriction Length Polymorphisms (RFLPs) and Simple Sequence Repeats (SSRs). Such techniques may be used to identify whether or not PH3AV was used to develop a hybrid. The Applicant also submits to the Examiner the journal article by Berry et al. (2002). This article discusses the probability of identifying the parents of the hybrid by SSR data when neither parent is known and without the use of pericarp analysis. A copy of the article by Berry et al. is attached to this Amendment and Request for

Reconsideration as Appendix B. The results of the experiment showed that using 100 SSR loci markers resulted in correct parental ranking of inbreds for 53 out of 54 hybrids. Applicant also points out that any breeder of ordinary skill in the art will know the identity of both parents used to produce a hybrid.

The Examiner rejects claims 14-17. Claims 14 and 17 have been cancelled. Claims 15 and 16 remain pending and are to methods of developing a maize plant through the utilization of PH3AV. Applicant points out that anyone of skill in the art would know how to utilize the well established breeding methods with PH3AV. Description of such occurs throughout the specification and descriptions can also be found in introductory plant breeding books.

The Examiner rejects claims 40-43. Claims 40-43 have been amended. Claim 40 is to the method of producing a first generation F1 PH3AV-derived maize plant. Applicant points out that this claim is to a method and requests that this rejection be withdrawn. Claim 41 is to the first generation F1 PH3AV-derived maize plant produced by the method of claim 40. The first generation F1, or hybrid, is identifiable through both breeding records and molecular marker techniques as discussed above. Claim 42 is to the method of selfing the first generation F1 PH3AV for successive filial generations. This is a basic and well known breeding methodology, and the use of this methodology with PH3AV is described in the specification on page 20, lines 1 to 15. Claim 43 is to plants derived from claim 42 that have at least 50% of their genetics derived from PH3AV. These claimed plants are clearly described by their method of production, which requires the use of PH3AV. Such plants must be produced through the use of PH3AV and the Examiner acknowledges that PH3AV is clearly identified. Further, Applicant has added the limitation of at least 50% inheritance from the PH3AV side of its pedigree to further emphasize the significant influence of PH3AV in the claimed product. Genetic inheritance has been accepted by both courts and governmental agencies as an accurate and reliable means of identification. In paternity cases courts routinely compel genetic testing of putative fathers to establish paternity, and federal law mandates that states have laws requiring that genetic test results be admissible

in such cases without the necessity for foundation testimony or other proof. 42 U.S.C. 666(a)(5)(F)(iii)(Supp. V 1999). In such cases, a child will, on average, inherit 50% genetic contribution from each parent. Similarly, the plants produced by the method of claim 42 will also, on average, inherit 50% genetic contribution from each parent.

Applicant requests that the Examiner examine the sufficiency of description of claim 43 with all of its claim limitations, including the limitation that the progeny be produced by the method of claim 42, with the use of PH3AV and retaining at least 50% genetic contribution from PH3AV. One of ordinary skill in the art would know how to cross PH3AV to develop an F1 hybrid and also how to self plants derived from the cross with PH3AV. In *Ex parte Parks*, 30 USPQ 2d 1234 (B.P.A.I. 1994), the Board of Appeals stated, "Adequate description under the first paragraph of 35 U.S.C. 112 does not require *literal* support for the claimed invention. Rather, it is sufficient if the originally-filed disclosure would have conveyed to one having ordinary skill in the art that an appellant had possession of the concept of what is claimed." Emphasis added. In *J.E.M. Ag. Supply*, the Supreme Court also acknowledged the value of a newly developed line in further breeding, when it stated that, "...a breeder can use a plant that is protected by PVP certificate to 'develop' a new inbred line while he cannot use a plant patented under §101 for such a purpose." Id. at 1873.

The Examiner states that, "the specification does not describe any molecular determinants that one would need to identify any genetic material as having been derived from PH3AV." Applicant traverses. As described in the specification, lines 3-23 on page 15, the seed deposit allows one of ordinary skill to run a molecular profile of PH3AV. Thus, one of ordinary skill in the art may test material they desire to use in breeding to determine if it is PH3AV. In order to expedite prosecution Applicant submits the molecular profile of inbred line PH3AV in the declaration of Dinakar Bhattramakki attached hereto as Appendix C. Further Applicant amends the specification to include such SSR profile. Such SSR profile is not new matter, as it is an inherent feature of inbred line PH3AV, a representative sample of which has been deposited with the ATCC. For

example, see Ex parte Marsili, Rosetti, and Pasqualucci, 214 USPQ 904 (1972), in which the Patent and Trademark Office Board of Appeals held that it was not [illegible] to amend the structure [illegible] when a more refined analytic investigation showed a corrected formula. The Board, relying on well established cases of In re Nathan et al, 51 CCPA 1059, 328 F.2d [illegible]5, 140 USPQ 601 (1964); In re Sulkowski, 487 F.2d 920, 180 USPQ 46 (CCPA 1973); Spero v. Ringold, 54 CCPA 1407, 377 F.2d 652, 153 USPQ 726 (1967), and Petisi et al v. Rennhard et al, 53 CCPA 1452, 363 F. 2d 903, 150 USPQ 669 (1966), concluded that the "products described, exemplified and claimed by Appellants inherently had and have now the structure given in the amendment in question. Consequently, the changes made in this amendment do not constitute new matter. Marsili at 906. Similarly, in the present case, inbred line PH3AV inherently had and still has the SSR marker profile being added. As described previously, one of ordinary skill in the art can use molecular markers to identify PH3AV, a transgenic version of PH3AV, a backcross conversion of PH3AV and the F1 plant of the transgenic version and backcross conversion of PH3AV.

The Examiner states that, "describing a plant that by saying it expresses 2 particular traits does not distinguish it from any other plant that expresses the same traits." Applicant points out that those claims referenced by the Examiner require the utilization of PH3AV to develop such plant. In order to expedite prosecution the claims identifying progeny by traits have been cancelled.

The Examiner also states that the morphological and physiological traits of PH3AV progeny are not described. The test of written description does not require a morphological and physiological description. Rather, it is whether subject matter was described in such a way to convey to one of ordinary skill in the art that the inventor had possession of the claimed invention. While PVP is distinct from patents, the scope of protection conferred by PVP provides a clear indication that breeders of ordinary skill in the art consider mutations, F1 hybrids, backcross conversions and transgenic conversions to be within the scope of the invention of the variety itself. See Appendix D. These derivatives, variants and closely related progeny easily and routinely created through the use of this newly

developed line are encompassed within the scope of the invention of the variety itself. The fact that the progeny have not been created does not prevent them from being protected by this mechanism. As stated in MPEP 2138.05 (2), "An invention may be complete and ready for patenting before it has actually been reduced to practice."

PH3AV-derived progeny are described by the fact that PH3AV is utilized in a breeding program to make the PH3AV-derived progeny. PH3AV gives genetic contribution to the PH3AV-derived progeny, as the genetics of PH3AV are described by ATCC deposit of PH3AV seed. By limiting the progeny to one breeding cross away from PH3AV and by limiting the progeny to those that contain at least 50% of their genetics from PH3AV, the Examiner's concern that the breadth of claims is not adequately described is addressed .

The Examiner also rejects claims 37-39 under 35 USC § 112, first paragraph. Claims 37-39 are directed to growing out an F1 hybrid in which PH3AV is a parent and searching for PH3AV inbred seed. Due to the imperfect process of seed production parent seed can sometimes be contained in the hybrid seed bag. This claim covers the method of searching for inbred PH3AV seed within a bag of hybrid seed. The method is clearly described in the specification on page 5, line 21 through line 7 on page 6. One of ordinary skill in the art can practice such a method without undue experimentation. The Applicant requests that the Examiner withdraw his rejection to claims 37-39.

The Examiner rejects claims to transgenic PH3AV plants and PH3AV plants comprising single gene conversions. New claims 50-57 are drawn to methods and to the products produced by those methods. The claims include the well known methods of producing backcross and transgenic conversion plants. The product by process claims are further limited by specified conversion or transgenic traits, which include the traits of insect resistance, herbicide resistance, disease resistance, waxy starch, and male sterility.

Applicant respectfully points out that examples of transgenes, genes, and traits that can be backcrossed into the PH3AV are given in the application on page 20, lines 16-34, and also on page 22, line 20, through page 32, line 4. At

the bottom of page 7 of the office action the Examiner suggests that the claims be amended to include a list of transgenes. In order to expedite prosecution now claim 51 and the list [illegible] conversions and transgenes. Claim 51 also specifies that PH3AV is used at least twice as a recurrent parent in the development of a backcross conversion plant. Breeders, by using molecular markers, may obtain up to 98% genome identity between the backcross conversion and the recurrent parent after two backcrosses. See Marker-assisted Selection in Backcross Breeding, O. [illegible]shaw, S.J. et al. Marker-assisted selection in backcross breeding. In: Proceedings Symposium of the Analysis of Molecular Data, August 1994, pp. 41-43. Crop Science Society of America, Corvallis, OR (1994) included as Appendix E. Inbred PH3AV transformed to comprise a transgene is also easily identifiable through the use of molecular markers. The transgenic version of PH3AV would have the same molecular profile as PH3AV, with the possible exception of a marker used in the profile that is located at the site of transgene insertion. However, in this case, the plethora of other identical markers would identify the line as a transgenic variant of PH3AV.

In the specification on page 4, lines 7-13, it states, "Backcrossing can be used to transfer a specific desirable trait from one inbred or source to an inbred that lacks that trait. This can be accomplished, for example, by first crossing a superior inbred (recurrent parent) to a donor inbred (non-recurrent parent), that carries the appropriate gene(s) for the trait in question. The progeny of this cross is then mated back to the superior recurrent parent followed by selection in the resultant progeny for the desired trait to be transferred from the non-recurrent parent." The method of backcrossing genes into an inbred maize plant is well known and well understood to one of ordinary skill in the art. The method has been successfully used since the 1950's (see pages 585-586 of Wych, 1988 included in the Information Disclosure Statement). In the specification, on page 20, lines 16-34, there is a description of how to backcross traits into PH3AV, which includes the claimed traits. Examples of how one of ordinary skill in the art can transfer a gene conferring a qualitative trait into a variety through

backcrossing is demonstrated by the fact that the commercial market now distributes a multitude of products produced in this manner. Such conversion [illegible] (1995) on page 334, submitted in the information disclosure statement, states that, "A backcross-derived inbred line fits into the same hybrid combination as the recurrent parent inbred line and contributes the effect of the additional gene added through the backcross." Wych (1988) on page 565-86, also submitted in the information disclosure statement, discusses how the male sterility trait is routinely backcrossed into an inbred line and how this is used to produce a sterile/fertile blend of an F1 hybrid in order to reduce seed production costs. In fact, many commercial products are produced in this manner, and those of ordinary skill in the art consider the F1 hybrid produced with the male sterile (backcross conversion) inbred to be the same variety as the F1 hybrid produced with the non-backcross conversion inbred.

As a result of the repeated use of the recurrent parent, the backcross conversion has many genetic alleles in common with the recurrent parent. Thus, genetic analysis may be used as a means of identifying the backcross conversion. The F1 hybrid made with a transgenic version or a backcross conversion of PH3AV is also identifiable by the use of genetic markers, because the hybrid would contain one set of alleles from each parent.

REJECTIONS UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

7.) The Examiner rejects claims 18-20 and 47-49 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant traverses the rejection.

Claims 18-20 and 47-49 have been cancelled and new claims 50-53 have been added. The Examiner states, "The specification teaches that single gene conversions, or introgression, of the disclosed maize plant through traditional breeding is contemplated (page 20, lines 15-30). However, the specification

does not teach any PH3AV plants comprising single gene conversions. It is not clear that single genes may be introgressed into the genetic background of a plant through backcross breeding."

The Examiner has cited Hunsperger, Kraft, and Eshed and stated that they "teach that it is unpredictable whether the gene or genes responsible for conferring a phenotype in one plant genotypic background may be introgressed into the genetic background of a different plant to confer a desired phenotype in said different plant." The Examiner states that, "Hunsperger et al. teach that the introgession of a gene in one genetic background in any plant of the same species, as performed by sexual hybridization, is unpredictable in producing a single gene conversion plant with a desired trait (column 3, lines 26-46)." Applicant respectfully disagrees that this is what is taught by Hunsperger et al. Hunsperger et al. teaches that a gene that results in dwarfism of a petunia plant can be incorporated into other genetic backgrounds of the petunia species (See column 2, line 67 to column 3, lines 1-4). Hunsperger et al. merely discusses that the level of the expression of that gene differed in petunia plants of different genetic backgrounds. Hunsperger et al. succeeded in incorporating the gene into petunia plants of different genetic backgrounds. Therefore, Hunsperger et al. support the fact that one can introgress a specific trait into a recurrent parent through backcross conversion. Applicant's specification provides ample disclosure of starting materials such as maize inbred PH3AV, a discussion of traditional breeding methods, and examples of transgenes and naturally occurring genes that may be used in such methods. Hallauer et al. (1988) on page 472, submitted in the information disclosure statement, state that, "For single gene traits that are relatively easy to classify, the backcross method is effective and relatively easy to manage." The teaching of Hallauer relates specifically to corn breeding and corn inbred line development.

The Examiner goes on to state that, "Kraft et al. teach that linkage disequilibrium effects and linkage drag prevent the making of plants comprising a single gene conversion, and that such effects are unpredictably genotypic specific and loci-dependent in nature (page 323, column 1, lines 7-15)."

Applicant disagrees that the article states such points. Kraft et al make no mention of a plant comprising a single gene conversion or the use of backcrossing. Further, Kraft et al. [illegible] fingerprinting in sugar beet, a crop other than maize. Kraft et al. state, on p. 226 first column, "The generality of our results for other crop species needs to be investigated."

It is understood by those of skill in the art that backcross conversions are routinely produced and do not represent a substantial change to a variety. The World Seed Organization, on it's web site, writes, "The concept of an essentially derived variety was introduced into the 1991 Act of the UPOV Convention in order to avoid plagiarism through mutation, multiple back-crossing and to fill the gap between Plant Breeder's Rights and patents." As determined by the UPOV Convention, essentially derived varieties may be obtained for example by the selection of a natural or induced mutant, or of a somaclonal variant, the selection of a variant individual from plants of the initial variety, backcrossing, or transformation by genetic engineering. The commercialization of an essentially derived variety needs the authorization of the owner on the rights vested in the initial variety." International Convention for the Protection of New Varieties of Plants, as amended on March 19, 1991, Chapter V, Article 14, Section 5(c), (emphasis added). A copy of the relevant portion of the UPOV Convention and the World Seed Organization web site is attached as Appendix D.

An example of how one of ordinary skill in the art can transfer a gene conferring a qualitative trait into a variety through backcrossing is demonstrated by the fact that the commercial market now distributes a multitude of products produced in this manner. Such conversion lines are easily developed without undue experimentation. Poehlman et al. (1995) on page 334, submitted in the information disclosure statement, states that, "A backcross-derived inbred line fits into the same hybrid combination as the recurrent parent inbred line and contributes the effect of the additional gene added through the backcross."

The Examiner goes on to state that, "Eshed et al. teach that in plants, epistatic genetic interactions from the various genetic components comprising

contributions from different genomes may affect quantitative traits in genetically complex and less than additive fashion (page 1315, column 1, line 1 to page [illegible] column 1, lines 1-5 of the Eshed et al. article it states, "Recent studies that detected epistasis of selected QTL in Drosophila (Long et al. 1995), soybean (Lark et al.1995) and maize (Doebley et al.1995; Cockerham and Zeng 1996) did not show a less-than additive trend." Emphasis added. Applicant also adds that transforming a qualitative trait does not require undue experimentation. Please note Hallauer et al. (1988) on page 472, submitted in the information disclosure statement, which states, "For single gene traits that are relatively easy to classify, the backcross method is effective and relatively easy to manage." Claim 51 has been amended to expedite prosecution. In claim 51, the genes transferred into PH3AV are now limited to the traits of herbicide resistance, insect resistance, disease resistance, male sterility, and waxy starch.

8.) Examiner rejects claim 14. Claim 14 has been cancelled to expedite prosecution.

In light of the amendments to the claims and the foregoing arguments the Applicant requests reconsideration of the rejection under the first paragraph of 35 U.S.C. 112.

REJECTIONS UNDER 35 U.S.C. § 102 and 103

9.) The Examiner states that, "Claims 14, 17, 33, 36, 41, and 43 remain rejected under 35 U.S.C. 102(e) as anticipated by or in the alternative, under 35 U.S.C. 103(a) as obvious over Kramer (U.S. Patent No. 6,124,534). " Applicant traverses the rejection.

Applicant has cancelled claims 14, 17, 33, and 36. Applicant has amended claims 41 and 43. Claim 41 is to the first generation F1 developed from crossing PH3AV with a second plant. Claim 43 is limited to progeny

produced by the method of claim 42, which requires the use of PH3AV, and is further limited to progeny deriving at least 50% genetic contribution from PH3AV. [illegible] rejected over prior art teaching the same product produced by a different process." PH1K2 is not PH3AV, nor can PH1K2 be created through the use of PH3AV with one breeding cross. Thus, claims 41 and 43 are not anticipated by PH1K2. As evidenced by the declaration of Stephen Smith submitted as Appendix F, both PH3AV and its progeny within the scope of claims 41 and 43 are distinct from PH1K2 taught in U.S. Patent No. 6,124,534.

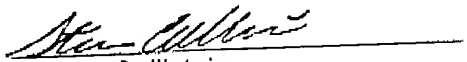
In light of the above, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection to claims 41 and 43 under 35 U.S.C. 102 (b) and 103(a).

Claims 1-2, 4-10, 15-16, 21, 23-27, 37-43, and 50-57 are now pending in the application. The amendments made herein do not in any way change the claim scope which the Applicant believes is allowable but is meant to hasten the issuance of the patent.

CONCLUSION

Applicant submits that in light of the foregoing amendments and the remarks, the claims 1-2, 4-10, 15-16, 21, 23-27, 37-43, and 50-57 requested. If it is felt that it would aid in prosecution, the Examiner is invited to contact the undersigned at the number indicated to discuss any outstanding issues.

Respectfully submitted,
Hartwig Wehrmann



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